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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,601	12/03/2003	Gudmundur Fertram Sigurjonsson	SIGU3012/JEK/JJC	4601

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EXAMINER

LEWIS, KIANDRA CHARLE

ART UNIT	PAPER NUMBER
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3772

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,601

Applicant(s)

SIGURJONSSON ET AL.

Examiner

Kiandra C. Lewis

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-23 and 25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3, 12, 19-21 and 25 is/are rejected.
7) ☒ Claim(s) 4-10, 13-18 and 23 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-10, 12-23 and 25 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 19 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/725,575; 10/725,633; 10/924,861 and 11/136,465. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are broader in some aspects and more specific in others.

Art Unit: 3772

4. Claim 1 of the application claims, a wound dressing, having an absorbent core, a skin adherent facing layer made of silicone gel, and a pressure sensitive adhesive layer. Claim 19 and 20 further recite the limitation that the facing layer is generally planar along the proximal surface. Application 10/725,633 claim 1 recites a wound dressing comprising an absorbent core that has proximal and distal surfaces, and a facing layer that is skin adherent. Claim 11 then goes on to teach that the facing layer is made of silicone gel. Claim 12 teaches that the silicone gel layer (facing layer) is substantially planar along a proximal surface thereof.

5. Application 10/725,575, claim 1 recites a wound dressing comprising an absorbent core having proximal and distal surface and a perforated skin adherant facing layer. Claim 14 of the copending application then goes on to teach that the facing layer is of silicone gel as recited in the 1 of the instant application.

6. Application 10/924,861 is not patentably distinct the instant application merely recites claims that are a broader recitation of the invention than that of the copending application, including the same limitation. The claims of the instant application recite the limitations as stated above. Claims 1-4, 11-14, and 17-20 of the copending application '861 further include the limitations that the dressing includes a plurality of preformed apertures arranged in a pattern, in addition to the layered dressing comprising a facing layer of silicone gel and an absorbent core.

7. The prior copending applications do not expressly state in the claim that there is a pressure sensitive adhesive layer but it would have been obvious to one skilled in the art to include such an adhesive layer because it is known in the art to include such a

Art Unit: 3772

layer in adhesive bandages for the purpose of securely attaching the bandage to the skin.

8. Copending application 11/136,465, recites the limitations of the claim 1 of the instant application in claims 1, 9 and 12. The copending application further recites in claim 13 that the facing layer also has a pressure sensitive adhesive. The instant application merely has claims that are a broader recitation of the copending application in some aspects and more specific in others.

9. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 2, 6, 12, 21, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. 5,160,328 in view of Rawlings et al. 4,657,006 and in further view of Lindqvist et al. 6,051,747.

Art Unit: 3772

As to claims 1, 12, 21, and 25 Cartmell et al. disclose a wound dressing having proximal and distal sides (Fig. 2), comprising an absorbent core having proximal and distal surfaces including central and border portions; a discrete skin adherent facing layer (16 or 17) the facing layer having a proximal surfaced and a distal surface directly secured to the absorbent core (14), said facing layer defining a region having a plurality of through extending apertures (col. 5, lines 39-41) arranged in a pattern; and a discrete pressure sensitive adhesive (20) layer applied directly to the facing layer on at least a segment of the proximal surface therefor only surrounding the region of the apertures (col. 4, lines 3-6 , lines 11-21) wherein the facing layer and the adhesive layer are contiguous and combine to define the entirety of the proximal sides of the dressing (col. 4, lines 19-23). Cartmell et al. do not expressly disclose that the facing layer is a cross-linked silicone gel. However Rawlings et al. disclose that the a wound dressing that contains in intermediate that is perforated. Rawlings et al. teach that intermediate layer is preferably a non-woven fabric that is formed from hydrophobic polymers. Cartmell et al. and Rawlings et al. are analogous because they are from the same field of endeavor of providing a patient with an absorbent dressing for a wound. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use a hydrophobic material as the facing layer in the invention of Cartmell et al. as taught by Rawlings et al. for the purpose of providing the additional support to the wound dressing. Rawlings et al. has not specifically stated "cross linked silicone gel", but the applicant has disclosed that the material is preferably hydrophobic. Lindqvist et al. go on to teach that the use of a hydrophobic cross linked silicone gel in

Art Unit: 3772

wound dressing (Fig. 1A, col. 1, lines 63-65). Lindqvist further teaches the need for a hydrophobic layer such as a cross linked silicone gel in a dressing for the purpose of preventing spontaneous reflux of absorbed fluid to the skin or the wound. The reference also teaches that it is possible to use other hydrophobic gels in wound dressings such as hydrophobic polyurethane gels. Therefore it would have been obvious to use a cross linked silicone gel as the facing layer because it is known in the art to use a hydrophobic layer in the a wound dressing.

As to claim 2, the above combination teaches the plurality of apertures of the facing layer (16, 17) to be located along a central portion (col. 5, lines 39-42).

As to claims 19 and 20, the proximal and distal surfaces of the facing layer are generally planar (patent '328, Fig. 2)

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. and Rawlings et al. and Lindqvist et al. as applied to claims 1 and 11 above, and further in view of Levin US 2003/0199800.

As to claim 3, Cartmell et al., Rawlings et al., and Lindqvist disclose the limitations of the base claim but do not expressly disclose that the border portion of the facing layer generally corresponding to the border portion of the absorbent core is substantially free of apertures. Levin however teaches that the border portion of the facing layer generally corresponding to the border portion of the absorbent core is substantially free

Art Unit: 3772

of said apertures (see figure 2). Therefore at the time of the invention it would have been obvious to one having ordinary skill in the art to modify the invention of Cartmell et al., Rawlings et al., and Lindqvist et al. by the limitation taught in Levin for the purpose of providing an attachment means that adhesive surface that is substantially leak free.

Allowable Subject Matter

13. Claims 4 -10,13-18, 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 4,614,183; 4,657,006; 4,699,146; 5,088,483; 5,489,262; 5,603,946; 5,653,699; 5,681,579; 5,738,642; 6,149,614; 6,663,584; 6,960,275; 6,977,323; 5,160,328; 5,244,457; 5,593,395.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3772

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kiandra C. Lewis whose telephone number is 571-272-7517. The examiner can normally be reached on Mon-Thurs 9AM-6PM and alternating Fridays 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/725,601

Page 9

Art Unit: 3772

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